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REMARKS

Claims 1,3 and 6 now stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Wong et al. (U.S. Patent No. 5,492,904).

Referring to Wong United States Patent 5,492,904 there is taught a pharmaceutical composition containing a combination of an angiotensin II receptor antagonist and calcium channel blocker. This is set out clearly in the summary of the invention and the detailed description of the invention. At column 4, line 33 the combination of the calcium channel blocker and the angiotensin II antagonist may further be combined with other agents such as lisinopril sodium. However Applicant's invention utilizes stabilized fosinopril sodium in combination with a lubricant selected from stearic acid and zinc stearate having the unexpected result of also stabilizing the tablet against degradation. The products of degradation are clearly set out in Applicant's disclosure at column 2 of the published application with respect to the various alternative lubricants. It has therefore been clearly determined by the Applicant and established by experimentation that stearic acid and zinc stearate when present as a lubricant in the tablet also had the unexpected advantage of minimizing degradation products when compared to the other well known lubricants, such as those listed.

It is clear from Wong and the examples taught therein that although he may have specified in his combination of calcium channel blocker and angiotensin II antagonist the further addition of an antihypertensive such as in one example fosinopril sodium, he had no understanding of the advantages of choosing lubricants with the minimum of degradation by products such as stearic acid and zinc stearate taught in the present application. This is clearly evidenced by the fact that in Wong's examples he did not appreciate the advantages and benefits of using

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zinc stearate or stearic acid as a lubricant since in formulating his capsules and tablets he elected to use magnesium stearate assuming that it would function as well as any of the other known lubricants yet having available to him the option of utilizing stearic acid. It is clear therefore that Wong did not understand the advantages of utilizing stearic acid or zinc stearate as a lubricant in his formulation since he did not appreciate the benefits resulting from using same over other well known lubricants.

Even though Wong may in fact at one remote location in his teaching refer to fosinopril sodium and lactose he only did so in context of his invention which is a composition including two components, one being the angiotensin II antagonist and the other being the calcium channel blocker. Fosinopril was stated only as one alternative in a list of many possible antihypertensives to be added to the combination. At no time however did Wong state that he appreciated that a lubricant such as stearic acid or zinc stearate could also be used to reduce the degradation products of his composition which would not include fosinopril in most cases. There is no discussion of this issue whatsoever in Wong, but which is included with Applicant's amended claims. Clearly, this being the case Wong lacks this understanding and teaching now present in Applicant's claim and therefore Wong cannot be considered to anticipate claim 1, 3 and 6 of the present application as required by the case law préciséd below.

#### ANTICIPATION

The following excerpts of U.S. case law represent Applicant's understanding of the test for novelty.

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In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986) ("It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact.").

In re Donohue, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985) ("an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.").

It is well settled that prior art under 35 USC Section 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it . . . . Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention . . . . Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling . . . . It is not, however, necessary that an invention disclosed in the publication shall have actually been made in order to satisfy the enabling requirement.

In Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. 209, 411 (Fed. Cir. 1984) ("exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference").

In Tights, Inc. v. Acme-McCravy Corp., 541, F.2d 1047, 191 U.S.P.Q. 305 (4th Cir. 1976); Saf-Gard Prods., Inc. v. Service Parts, Inc., 532 F.2d 1266, 190 U.S.P.Q. 455 (9th Cir. 1976); Shanklin Corp. v. Springfield Photo Mount Co., 521 F.2d 609, 187 U.S.P.Q. 129 (1st Cir. 1975) ("To anticipate under section 102, a prior art reference must disclose all the

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elements of the claimed invention or their equivalents functioning in essentially the same way.").

*In re Sun*, 31 USPQ 2d 1451, 1453 (Fed. Cir. 1993) (unpublished)

Under section 102(b), anticipation requires that the prior art reference disclose, either expressly or under the principles of inherency, every limitation of the claim. . . .

But to be prior art under section 102(b), a reference must be enabling. . . . That is, it must put the claimed invention in the hand of one skilled in the art. . . . The examiner bears the burden of presenting at least a *prima facie* case of anticipation.

*Helifix Ltd. v. Blok-Lok, Ltd.*, 54 USPQ 2d 1299, 1304 (Fed. Cir. 2000)

"[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Donohoe*, 766 F.2d at 533, 226 USPQ at 621.

*In re Wilder*, 166 USPQ 545, 548 (C.C.P.A. 1970)

Simply stated, a prior publication or patent description will be considered as anticipatory when its disclosure is at once specific and enabling with regard to the particular subject matter at issue. . . . However, such disclosure may yet be held not to legally anticipate the claimed subject matter if it is found not to be sufficiently enabling, in other words, if it does not place the subject matter of the claims within "the possession of the public."

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*Ciba-Geigy Corp. v. Alza Corp.*, 37 USPQ 2d 1337, 1341 n.3 (Fed. Cir. 1995) (unpublished)

An anticipatory reference must be enabling, *see Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 U.S.P.Q.2D (BNA) 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909, 96 L. Ed. 2d 382, 107 S. Ct. 2490 (1987), so as to place one of ordinary skill in possession of the claimed invention. *In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2D (BNA) 1655, 1657 (Fed. Cir. 1990); *see Seymour v. Osborne*, 78 U.S. 516, 555, 20 L. Ed. 33 (1870) ("The knowledge supposed to be derived from the publication must be sufficient to enable those skilled in the art or science to understand the nature and operation of the invention.").

It is clearly required that for a patent to anticipate an invention it must be enabling and include each and every limitation of that invention as setout in the claims. Applicant's amended claim 1 now clearly distinguishes over Wong, which cannot anticipate nor render obvious Applicant's claims 1, 3 and 6 as amended since Applicant's combination is simply not taught nor enabled in Wong for the reasons set out above. Clearly Wong did not even appreciate the problem addressed by Applicant as taught in claim 1 as amended namely:

*A pharmaceutical tablet comprising stabilized fosinopril sodium and a lubricant selected from stearic acid and zinc stearate wherein the presence of the selected lubricant results in products of degradation for the tablet in a range of less than 2.5%.*

Claims 2 and 7 now stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Wong (U.S. Patent No. 5,492,904) in view of Sjoerdsma (U.S. Patent No. 4,189,492). Applicant is not seeking to protect claims 2 and 7 in independent form. If claim 1 as amended

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is held allowable, which should b the case in view of Applicant's amendments , then claim 2 and 7 should be allowable as well.

Referring now to Sjoerdsma (U.S. Patent No. 4,189,492) hereinafter referred to as '492, there is taught a therapeutic antihypertensive composition for reducing blood pressure in mammals. Particularly his invention relates to novel therapeutic compositions of lofexidine. A review by Applicant of the specification results in a conclusion that fosinopril sodium is not discussed whatsoever in the specification of the '492 reference. The Examiner has stated that it would be obvious to combine the teachings of Wong with the '492 reference. Zinc stearate is not taught in Wong as admitted by the Examiner and therefore has relied on the teachings of the '492 reference.

The Examiner has stated that where the general conditions of the claim are disclosed in the prior art it is not inventive to discover the optimum values by routine experimentation. This allegation is only true if one skilled in the art would consider the '492 reference prior art to Applicant's invention, and whether in fact one skilled in the art would combine the teachings of Wong and the '492 reference. Clearly Wong had available to him the teachings of the '492 reference and did not choose to identify zinc stearate as a lubricant. Even if one were to combine the teachings of Wong and the '492 reference it is clear from the examples of the '492 reference that Sjoerdsma clearly had no understanding of the advantages of utilizing one lubricant over the other and particularly zinc stearate and stearic acid. This is evidenced by the fact that in examples 1 and 2 the inventor chose to use calcium stearate as a lubricant, which is identified in Applicant's teachings clearly as one of the worst possible choices that he could have made namely calcium stearate as a lubricant in terms of the generation of degradation products set out on page 4 of Applicant's disclosure.

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The traditional test enunciated in Graham vs. John Deere Company 383 U.S. 1, 148 U.S.P.Q. 459 1966, for Section 103 nonobviousness requires the fact finder to make several determinations. The test provides that the scope and content of the prior art be determined, the differences between the prior art and the claims at issue be ascertained, and the level of ordinary skill in the pertinent art be resolved. Thus, the patentability of the claims at hand must stem from the fact that the specific combination of the claimed elements was not disclosed in the prior art and the additional allegation that the specific combination of claimed elements was nonobvious to one of ordinary skill in the art.

Clearly, the prior art does not suggest or provide any reason or motivation to make such a modification as purported by the Examiner. With reference to In Re: Regal, 526 F. 2d 1399, 1403 n. 6, 188 USPQ 136, 139 n. 6 (CCPA 1975).

*"There must be some logical reason apparent from positive, concrete evidence of record which justifies a combination of primary and secondary references".*

In Re: Geiger, 815 F. 2d 686, 688, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987) (obviousness can not be established by combining pieces of prior art absence some "teachings, suggestion, or incentive supporting the combination"); In Re: Cho, 813 F. 2d 378, 382, 1 USPQ 2d 1662, 1664 (Fed. Cir. 1987) ("discussing the Board's holding that the artisan would have been motivated to combine the references").

Therefore, it Applicant's view there is no evidence of motivation in the prior art, either within the references themselves, or knowledge generally available to one of ordinary skill in the art,

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to make the purported changes suggested by the Examiner to arrive at the claimed subject matter.

Respectfully, the Examiner is creating a 20/20 hindsight reconstruction using Applicant's invention as a blue print to allegedly find elements of Applicant's combination in the prior art. This is not permissible as set out below.

*In re Oetiker*, 24 USPQ 2d 1443, 1446 (Fed. Cir. 1992)

The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. **There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination.**

(emphasis added) That knowledge can not come from the applicant's invention itself.

*ATD Corporation v. Lydall, Inc.*, 48 USPQ 2d 1321, 1329 (Fed. Cir. 1998)

Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. **There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor.** (emphasis added)

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In Re: Fritch, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992)

"Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board. Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious(emphasis added). The court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

In Re: Rouffet, 47 U.S.P.Q. 2d 1453 (Fed. Cir. 1998)

*"As this court has stated, "virtually all [inventions] are combinations of old elements." Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." Sensonics, Inc. v. Aerasonic Corp., 81 F.3d 1566, 1570, 38 USPQ 2d 1551, 1554 (Fed. Cir. 1996).*

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*To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. (emphasis added)*

*This court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In this case, the Board relied upon none of these. Rather, just as it relied on this high level of skill in the art to overcome the differences between the claimed invention and the selected elements in the references, it relied upon the high level of skill in the art to provide the necessary motivation. The Board did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the field of art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.*

*Because the Board did not explain the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no knowledge of Roussel's invention to make the combination,*

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*this court infers that the examiner selected these references with the assistance of hindsight. This court forbids the use of hindsight in the selection of references that comprise the case of obviousness.*

(emphasis added) See *In re Gorman*, 933 F.2d 982, 986, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991). *Lacking a motivation to combine references, the Board did not show a proper prima facie case of obviousness. This court reverses the rejection over the combination of King, Rosen and Ruddy.*

Therefore clearly neither Wong nor Sjoerdsma understood the problem solved by Applicant's amended claim 1, that is the use of either stearic acid or zinc stearate as a lubricant present also to limit the amount of degradation products to below 2.5% which is substantially less than the known lubricant for this purpose, sodium stearyl fumarate.

How then can any combination proposed by the Examiner of Wong and the '492 reference result in Applicant's invention as set out in his amended claim set, if neither nor Wong '492 appreciated the problem. The motivation in the art is therefore clearly lacking.

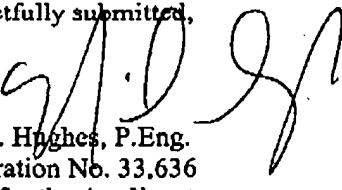
Applicant therefore has assessed the prior art cited by the Examiner and has made amendments to overcome his alleged prior art rejections as well as providing arguments with regard to the inappropriateness of the Examiner's remarks in misreading of the prior art and attempting to create an improper 20/20 hindsight reconstruction. Applicant has also fully refuted the Examiner's combination of the prior art and set out according to the accepted principles of *Graham v John Deere* cited above and identified the differences in the claims as amended that distinguish over the prior art cited by the Examiner and the lack of motivation in the art nor expectation of success required by the courts in his attempt to create an improper hindsight reconstruction. Full reconsideration is respectfully requested.

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No fees should be due with this amendment and addition of two new claims since the total number of claims in the case is 18. However if any claims fees or any other fees should be determined to be required by the Examiner he is requested to access Applicant's Agent's deposit account No. 08-3255 for this purpose and advise Applicant's Agent accordingly.

If the Examiner has any questions, he is requested to contact Neil H. Hughes at (905) 771-6414 at his convenience.

Respectfully submitted,

  
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NHH:jlh  
Enclosures